UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, and the STATES OF CALIFORNIA, DELAWARE, FLORIDA, ILLINOIS, INDIANA, MICHIGAN, NEVADA, NEW MEXICO, NEW YORK, TENNESSEE, TEXAS and the DISTRICT OF COLUMBIA, EX. REL. DAVID MOORE,

Plaintiffs,

-against-

GLAXOSMITHKLINE, LLC,

Defendant.

MEMORANDUM DECISION AND ORDER

06 Civ. 6047 (BMC)

COGAN, District Judge.

Before the Court is defendant GlaxoSmithKline, LLC's ("GSK") motion to dismiss relator David Moore's ("plaintiff") Second Amended Complaint ("complaint") in this *qui tam* action brought under the False Claims Act ("FCA"), 31 U.S.C. § 3729(a)(1), and various false claims provisions of state law. GSK argues that the complaint should be dismissed for failure to plead fraud with particularity pursuant to Federal Rule of Civil Procedure 9(b), and for failure to state a claim pursuant to Rule 12(b)(6). For the reasons set forth below, GSK's motion to dismiss [43] is granted and the complaint is dismissed.

BACKGROUND

At some point prior to 2003, plaintiff was employed by GSK as a Senior Executive in sales, where he was responsible for marketing the company's HIV drugs in Manhattan. GSK is the United States operating subsidiary of GlaxoSmithKline plc, a worldwide pharmaceutical

company, headquartered in the United Kingdom, which manufactures and sells various drugs, including those used in the treatment of HIV/AIDS.

Plaintiff initiated this action in 2006 and served his complaint upon the Government. On August 24, 2012, the Government filed notice of its decision not to intervene in this case. Plaintiff served the complaint on GSK and has proceeded with the action, acting on behalf of the United States and several states.

The gravamen of plaintiff's complaint is that GSK induced physicians, through a purported kickback scheme, to issue prescriptions for certain HIV medications manufactured by GSK. This, in turn, caused pharmacies to submit false claims for reimbursement to Medicaid, Medicare, the AIDS Drug Assistance program, and other government health care programs. Plaintiff also appears to allege that GSK's kickbacks caused physicians to submit provider certifications which falsely stated that the physicians were in compliance with the federal and state anti-kickback laws. Absent these false certifications, plaintiff alleges that the Centers for Medicare and Medicaid Services ("CMS") and state health care programs would not have reimbursed the physicians for issuing the prescriptions.[1]

While plaintiff's allegations regarding the submission of false claims to the Government are sparse and, where they do exist, unclear, plaintiff describes GSK's alleged kickback scheme in great detail. According to plaintiff, during his employ at GSK, GSK manufactured and sold the HIV medications known as Epzicom, Lexiva, and Trizivir, which were sold in New York and other regions of the country. Plaintiff alleges that the medical community, including the Department of Health and Human Services (HHS), did not consider these medications to be "preferred" medication. Epizcom, for example, was considered an "alternative" to the preferred

[1] The Court notes that the complaint is unclear as to who exactly submitted claims for reimbursement – the medical providers who prescribed the drugs at issue, the pharmacists who filled those prescriptions, or both groups of individuals.

medications, and Trizivir was considered an "inferior" treatment option. Plaintiff alleges that one of the ingredients in Epzicom – abacavir – caused many HIV patients (approximately 5-8% of those who take Epzicom) to experience a dangerous side effect known as "hyper-sensitivity reaction," that can cause death; those who experience this must discontinue Epzicom and avoid other medications that contain abacavir. Trizivir, which also contains abacavir, had been proven to be less effective at combating HIV than other regimens. HHS had, since at least July 2003, advised that Trizivir should not be prescribed for an HIV patient unless a preferred or alternative to a preferred treatment could not or should not be prescribed.

Plaintiff alleges that despite Epzicom's "second-tier status," which makes it medically appropriate for less than 2% of HIV patients, Epzicom was being prescribed at a rate of approximately 8% for new HIV patients across the United States, and approximately 12.8% for new HIV patients in Brooklyn. Certain doctors associated with GSK prescribed Epzicom at rates anywhere from 20%-35%. During the first year after the FDA approved the drug for sale in the United States, sales of Epzicom climbed steeply from $28.5 million in the first quarter of 2005 to $53.2 million in the final quarter. The alleged reason for this unexpected volume of Epzicom prescriptions is that GSK induced doctors to prescribe these drugs.

Plaintiff further alleges that GSK's payments to physicians were thinly disguised as payments for something other than writing prescriptions, such as excessive honoraria for conducting small patient or community programs, unrestricted "educational grants," and excessive payments for participating in meetings of an "advisory board," "key opinion leaders" or "clinical trials." Plaintiff claims that both GSK and the physicians understood that these payments were contingent on the physicians' prescribing of GSK's medication to a high percentage of that doctor's patients.

Despite the fact that GSK's own internal policy recommended that GSK should not pay more than $300 to physicians for half-day educational programs, doctors, such as Dr. Andre Brutus, were paid $2,500 per "patient program." Plaintiff alleges that as of January, 2007, Dr. Brutus, a Brooklyn physician, wrote more Epzicom prescriptions than any other doctor in the country. Plaintiff includes statements made by several doctors about the large sums they received from GSK for simply showing up to dinner, going for "a talk," or sometimes doing absolutely nothing. Plaintiff alleges that GSK would sometimes use a third-party company to funnel these checks to physicians so as to conceal the nature of the payments. Plaintiff further alleges that one of GSK's representatives told a doctor, "You give me more Epivir and I'll give you a $35,000 grant." The doctor allegedly received the grant and did nothing in return other than writing prescriptions for GSK HIV medications. As one doctor explained to plaintiff, GSK was simply "paying for a prescription."

All of the states on whose behalf plaintiff is suing allegedly participated, during the relevant time, in Medicaid and ADAP programs under which they paid for medications prescribed for HIV patients. Plaintiff estimates that for approximately 80% of the patients in this country who use these medications, the drugs are paid for by the federal, state, and/or municipal governments, under the federal-state Medicaid or ADAP programs, or under other federal, state, or municipal health insurance programs.

DISCUSSION

The FCA allows private individuals, known as "relators," to file *qui tam* actions on behalf of the United States. 31 U.S.C. §§ 3729-3733. Liability under the FCA attaches to anyone who:

> (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval; [or]

> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government.

31 U.S.C. § 3729(a)(1)-(2). "Claim" is defined as

> any request or demand, whether under a contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse each contractor, grantee or other recipient for any portion of the money or property which is requested or demanded.

31 U.S.C. § 3729(c). Because an FCA violation does not exist without the submission of a false claim, the existence of a false claim is an essential element of a FCA violation. United States ex rel. Clausen v. Lab. Corp. of Am., Inc., 290 F.3d 1301 (11th Cir. 2002).

The Second Circuit has held that the FCA is an "anti-fraud statute," and therefore claims brought under the FCA "fall within the express scope of Rule 9(b)" of the Federal Rules of Civil Procedure. See Gold v. Morrison-Knudsen Co., 68 F.3d 1475, 1476–77 (2d Cir. 1995) (citing cases identifying courts that have routinely required FCA claims to comply with Rule 9(b)).

GSK's principal argument is that plaintiff's complaint should be dismissed for failure to plead the details of a specific false claim as required by Rule 9(b).[2] Although "the Second Circuit has not explained exactly what Rule 9(b) demands of FCA claims," the weight of authority from district courts within this Circuit is that where an alleged FCA violation involves the submission of a false claim to the Government for reimbursement, the details of that false claim must be pled with particularity. U.S. ex rel. Mooney v. Americare, Inc., No. 06–CV–1806, 2013 WL 1346022 at *3 (E.D.N.Y. Apr. 3, 2013) (collecting cases); see also United States ex rel. Piacentile v. Novartis, No. 1:04-cv-4265 (NGG) (E.D.N.Y. Feb. 8, 2011) ECF No. 84; United States ex rel. Chapman v. Office of Children & Family Servs. of State of New York, No.

[2] Because the Court is dismissing the complaint for failure to comply with Rule 9(b), it need not address GSK's additional argument that plaintiff failed to plead a nationwide scheme.

1:04-CV-1505, 2010 WL 610730 (N.D.N.Y. Feb. 16, 2010), aff'd sub nom. Chapman v. Office of Children & Family Servs. of the State of New York, 423 F. App'x 104 (2d Cir. 2011); United States ex rel. Polansky v. Pfizer, Inc., No. 04-CV-0704 (ERK), 2009 WL 1456582, at *4 (E.D.N.Y. May 22, 2009) (concluding that the complaint must allege with particularity the "who, what, when, where and how of the alleged fraud") (quoting Thompson v. Columbia/HCA Healthcare Corp., 125 F.3d 899, 903 (5th Cir. 1997)); United States ex rel. Reynolds v. Sci. Applications Int'l Corp., No. 07 CV 4612 (GBD), 2008 WL 2566747 (S.D.N.Y. June 26, 2008).

A number of district courts in this Circuit base this particularity requirement on the standard articulated by the First Circuit in United States ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220 (1st Cir. 2004), abrogated on other grounds by Allison Engine Co., Inc. v. U.S. ex rel. Sanders, 553 U.S. 662 (2008). This view is shared by several other Circuits. See United States ex rel. Nathan v. Takeda Pharmaceuticals N. Am., Inc., 707 F.3d 451 (4th Cir. 2013); United States ex rel. Bledsoe v. Cmty. Health Sys., Inc., 501 F.3d 493, 504 (6th Cir. 2007); United States ex rel. Sikkenga v. Regence Blue Cross BlueShield of Utah, 472 F.3d 702 (10th Cir. 2006); United States ex rel. Clausen v. Lab. Corp. of Am., Inc., 290 F.3d 1301 (11th Cir. 2002).

In addition to pleading fraud with particularity, the complaint must allege sufficient facts to create "the reasonable inference that the defendant is liable for the misconduct alleged." See Ashcroft v. Iqbal, 556 U.S. 662, 679, 129 S. Ct. 1937, 1940 (2009). Thus, in order for plaintiff to defeat a motion to dismiss, the fraudulent scheme must be pled adequately, and the false claim element must be pled with particularity. See Polansky, 2009 WL 1456582, at *5 ("a [plaintiff] cannot circumscribe the Rule 9(b) pleading requirements by alleging a fraudulent scheme in

detail and concluding, that as a result of the fraudulent scheme, false claims must have been submitted.").

Plaintiff argues that the "prevailing standard" does not require that he plead the specifics of an actual claim. Rather, this relaxed standard only requires that he show reliable indicia that false claims were submitted. See e.g., United States ex rel. Grubbs v. Kanneganti, 565 F.3d 180, 189 (5th Cir. 2009) (holding that a *qui tam* plaintiff need not allege the time, place, and contents of the false representation in every case, because requiring this level of detail is "one small step shy of requiring production of actual documentation with the complaint . . ."); United States ex rel Schumann v. AstraZeneca PLC, No. 03-5423, 2010 WL 4025904 (E.D. Pa. Oct. 13, 2010) (claims under the FCA "need only show the specifics of a fraudulent scheme and provide an adequate basis for a reasonable inference that false claims were submitted as part of that scheme") (quotation omitted).

Based on his view of the law, plaintiff argues that two of his allegations suffice to provide an adequate basis for the Court to reasonably infer that false claims were submitted: first, that GSK sold hundreds of millions of dollars of Epzicom and Trizivir in the U.S. each year and that "for approximately 80% of the patients in the United States who use GSK HIV medications, the medicine is paid for by [government health programs]"; and second, that a Dr. Williamson told plaintiff she was aware that GSK was asking doctors to write Epzicom prescriptions in return for $500 and that pharmacies that provide the medications charged the costs to Medicaid, even though GSK should be providing the medications for free.

As an initial matter, the Court rejects plaintiff's interpretation of the pleading burden under Rule 9(b). Unless a false claim is actually presented to the government, even where "the practices of an entity that provides services to the Government may be unwise or improper, there

is simply no actionable damage to the public fisc as required under the False Claims Act." Karvelas, 360 F.3d at 232 (quoting Clausen, 290 F.3d at 1311). The underlying schemes and wrongful conduct that lead to submission of a fraudulent claim are "circumstances constituting fraud" which must also be pled with particularity under Rule 9(b). See id. But a certification of eligibility or request for payment from the government, and the resulting potential damage to the public fisc, is an essential element of an FCA action, and cannot be adequately pleaded absent particularized allegations concerning the actual false claims submitted to the government.

Although it appears that plaintiff has alleged adequately the details of the purported fraudulent scheme, there is nothing in the complaint alleging with particularity that a claim was submitted to the Government for reimbursement. While there is no mandatory checklist, "details concerning the dates of the claims, the content of the forms or bills submitted, their identification numbers, the amount of money charged to the government, the particular goods or services for which the government was billed, the individuals involved in the billing, and the length of time between the alleged fraudulent practices and the submission of claims based on those practices are the types of information that may help a relator to state his or her claims with particularity." Karvelas, 360 F.3d at 233. It is insufficient to allege that the submission of a false claim is merely conceivable or even likely. Here, plaintiff has failed to allege details of either a specific claim for payment that was submitted to the Government by either a medical provider or a pharmacist, *or* the specific details of an actual Medicaid/Medicare provider certification form signed by a particular physician. Plaintiff has alleged neither available false claim with particularity and therefore has not met the requirements of Rule 9(b).

Even if the Court were to adopt the relaxed Rule 9(b) standard, plaintiff's complaint would still fail because there are no facts that substantiate plaintiff's 80% approximation or his

vague allegation that according to one doctor "pharmacies that provide the medications charge the costs to Medicaid . . . ." See United States ex rel. Underwood v. Genentech, Inc., 720 F. Supp. 2d 671, 676 (E.D. Pa. 2010) ("They need not . . . plead the date, place or time of the fraud, so long as they use an alternative means of injecting precision and some measure of substantiation into their allegations of fraud.") (citing Rolo v. City Investing Co. Liquidating Trust, 155 F.3d 644, 658 (3d Cir. 1998) (abrogated on other grounds); United States ex rel. Lemmon v. Envirocare of Utah, Inc., 614 F.3d 1163 (10th Cir. 2010) (plaintiff was permitted to rely on personal accounts of false claims being submitted as a part of an existing government contract even though plaintiff failed to identify a specific false claim); Hill v. Morehouse Medical Associates, Inc., 2003 WL 22019936 (11th Cir. Aug. 15, 2003) (concluding that plaintiff adequately claimed the submission of false claims based on her first-hand accounts and observations while employed in the billing department of the defendant, even though she could not allege a specific claim). Moreover, he fails to allege that any of the particular physicians who allegedly received GSK kickbacks signed a provider certification as a condition for reimbursement.

The Court recognizes that the Second Circuit has held that Rule 9(b)'s pleading with particularity standards may be relaxed when "facts are peculiarly within the opposing party's knowledge." Boykin v. Keycorp, 521 F.3d 202, 215 (2d Cir. 2008). In the instant case, nothing in the complaint indicates that the details of a specific false claim are peculiarly within GSK's knowledge. GSK may have had intimate knowledge of the alleged kickback scheme, but there is no reason to believe that GSK had any knowledge of false claims that were submitted by either third-party medical providers or pharmacists.

Furthermore, this is not a case "involv[ing] complex or extensive fraudulent schemes," in which "courts have 'relaxed' Rule 9(b)'s pleading requirements." See U.S. ex rel. Taylor v. Gabelli, 345 F. Supp. 2d 313, 327 (S.D.N.Y. 2004) (complex bid-rigging scheme). The alleged kickback scheme itself seems rather straight-forward. As one doctor allegedly characterized the scheme, doctors got paid for writing prescriptions. That plaintiff described the alleged kickback scheme in great detail does not necessarily mean the scheme itself is complicated. Plaintiff has thus failed to meet the requirement of Rule 9(b) and the Court finds that there is no basis for relaxing the pleading standard.

Finally, the Court observes that plaintiff did not request leave to amend his complaint pursuant to Rule 15(a) of the Federal Rules of Civil Procedure and there is no reason for the Court to grant leave to amend *sua sponte* because amendment would be futile. See Green v. Mattingly, 585 F.3d 97 (2d Cir. 2009); In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 220-21 (2d Cir. 2006). Plaintiff has alleged no facts that indicate that he would ever be in a position to allege plausibly the fact that a false claim was submitted. Furthermore, plaintiff has essentially conceded in his opposition that he is not in possession of such information, relying on his argument that his allegations constitute "reasonable indicia" that a false claim was submitted. Leave to amend is therefore denied.

CONCLUSION

GSK's motion to dismiss the FCA and related state law causes of action is granted, and the complaint is dismissed.

SO ORDERED.

Digitally signed by Brian M. Cogan

U.S.D.J.

Dated: Brooklyn, New York
October 16, 2013